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09/786,481	03/05/2001	Frank Hulstaert	11362.0034.P	8708

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EXAMINER

NICHOLS, CHRISTOPHER J

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 09/02/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/786,481

Applicant(s)

HULSTAERT ET AL.

Examiner

Christopher Nichols, Ph.D.

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1, 5, 8 and 11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☒ Claim(s) 5, 8, 11 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 March 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other:

## DETAILED ACTION

### *Status of Application, Amendments, and/or Claims*

1. The Amendment filed 8 August 2003 (Paper No. 11) has been received and entered in full. Claims 6 and 9 have been amended and claims 1 and 5 have been amended. Claims 1, 5, 8, and 11 are under examination.

### *Withdrawn Objections And/Or Rejections*

2. The rejection of claims **6 and 9** under 35 U.S.C. §112 ¶1 as set forth at pp. 4-17 ¶13-61 in the previous Office Action (Paper No. 9, 3 April 2003) is hereby *moot* in view of Applicant's cancellation of said claims (Paper No. 11, 8 August 2003).
3. The rejection of claim **1** under 35 U.S.C. §112 ¶1 as set forth at pp. 4-17 ¶13-61 in the previous Office Action (Paper No. 9, 3 April 2003) is hereby *withdrawn in part* in view of Applicant's amendments (Paper No. 11, 8 August 2003).
4. Claims **1, 5, and 11** are rejected under the judicially created doctrine of obviousness-type double patenting as set forth at pp. 18-19 ¶63-66 in the previous Office Action (Paper No. 9, 3 April 2003) is hereby *withdrawn* in view of Applicant's amendments (Paper No. 11, 8 August 2003).
5. Claims **1, 8, and 11** under the judicially created doctrine of obvious-type double patenting as set forth at pp. 19 ¶67-70 in the previous Office Action (Paper No. 9, 3 April 2003) is hereby *withdrawn* in view of Applicant's amendments (Paper No. 11, 8 August 2003).

### *Maintained Objections And/Or Rejections*

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for *a method for aiding in the detection of CNS (central nervous system) damage in an individual, said CNS damage being caused by benign primary brain tumors, malignant primary brain tumors; by anoxia or ischemia, said method comprising the steps as set forth in claim 1*, does not reasonably provide enablement for *quantification of said damage using the method as set forth in claim 1*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims as set forth at pp. 4-17 ¶¶13-61 in the previous Office Action (Paper No. 9, 3 April 2003).

7. Applicant traverses the rejection of claim 1 under 35 U.S.C. 112, first paragraph on the following grounds: (a) “invasions or metastasis of the CNS” has been removed, (b) the currently amended claims are drawn only to specifically defined forms of CNS damage, (c) the instant Application shows that tau levels are elevated with respect to a control, for some maladies, including but not limited to those specifically enumerated in the instant claims, (d) the instant invention is drawn to “aiding in the detection” of the enumerated maladies, (e) “early” has been removed from claim 1, and (f) the instant invention is drawn to the specifically enumerated maladies and not general CNS damage. Applicant’s arguments have been taken into consideration and are not found persuasive for the following reasons.

Art Unit: 1647

8. Concerning “(a)”, the rejection is *moot* concerning this point due to Applicant’s amendments (Paper No. 11, 8 August 2003).
9. Concerning “(b)”, this argument is persuasive and the rejection has been amended as noted above in view of Applicant’s amendments and arguments (Paper No. 11, 8 August 2003).
10. Concerning “(c)”, this argument is persuasive and the rejection has been amended as noted above in view of Applicant’s amendments and arguments (Paper No. 11, 8 August 2003).
11. Concerning “(d)”, this argument is persuasive and the rejection has been amended as noted above in view of Applicant’s amendments and arguments (Paper No. 11, 8 August 2003).
12. Concerning “(e)”, the rejection is *moot* concerning this point due to Applicant’s amendments (Paper No. 11, 8 August 2003).
13. Concerning “(f)”, this argument is persuasive and the rejection has been amended as noted above in view of Applicant’s amendments and arguments (Paper No. 11, 8 August 2003).
14. While providing sufficient guidance in the specification for the detection of elevated tau levels in the CSF (those exceeding the corresponding control patient samples), no evidence or guidance is given to properly correlate any given tau level with the severity of the injuries listed in claim 1.
15. Thus the rejection of claim 1 under 35 U.S.C. 112, first paragraph, is maintained in part.

#### ***New Objections And/Or Rejections***

##### ***Claim Objections***

16. Claims 5, 8, and 11 are objected to because of the following informalities: said claims depend from a rejected claims. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

17. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: how are the CSF tau levels determined in the patient and control populations.

***Summary***

18. Claim 1 is hereby rejected.

19. The following articles, patents, and published patent applications were found by the Examiner during the prior art search and are here made of note:

- a. US 6589746 B1 (8 July 2003) Zemlan
- b. WO 99/45393 (10 September 1999) Zemlan & Campbell

20. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

21. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

Art Unit: 1647

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 1647

### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is 703-305-3955. The examiner can normally be reached on Monday through Friday, 8:00AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Gary Kunz, Ph.D.** can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. The fax phone numbers for the customer service center is 703-872-9305

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

CJN  
August 27, 2003

*Elizabeth C. Kemmerer*

ELIZABETH KEMMERER  
PRIMARY EXAMINER